FORM PTO-1390 (REV. 5-93)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

5860

U.S. APPLICATION NO.

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

09/029251

INT	ERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED		
PCT/FR96/01346		September 4, 1996	September 5, 1995		
TITE	E OF INVENTION				
	tilumen Catheter Particul	arly For Hemodialysis			
	ICANT(S) FOR DO/EO/US				
1	hierry Pourchez				
App	licant herewith submits to the Unit	ed States Designated/Elected Office (DO/EO/US) the fo	llowing items and other information.		
1.	This is a FIRST submission of	items concerning a filing under 35 U.S.C. 371.			
2.	2. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.				
3.	This express request to begin examination until the expirat	national examination procedures (35 U.S.C. 371(F)) at ion of the applicable time limit set in 35 U.S.C. 371	t any time rather than delay (b) and PCT Articles 22 and 39(l).		
4.	A proper Demand for Internati date.	onal Preliminary Examination was made by the 19th mont	th from the earliest claimed priority		
5.	A copy of the International A	pplication as filed (35 U.S.C. 371(c)(2)):			
	a. 🔯 is transmitted herewi	th (required only if not transmitted by the internation	onal Bureau).		
	b. X has been transmitted	by the International Bureau.			
	c. 🗌 is not required, as t	he application was filed in the United States Receiving	ng Office (RO/US).		
6.	A translation of the Internat	ional Application into English (35 U.S.C. 371(c)(2)).			
² 7.	Amendments to the claims of t	he International Application under PCT Article 19 (35	u.s.c. 371(c)(3)):		
F:	a. are transmitted herew	ith (required only if not transmitted by the Internati	onal Bureau).		
	b. have been transmitted	by the International Bureau.			
: /	c. have not been made; h	омечег, the time limit for making such amendments has	NOT expired.		
i.	d. have not been made an	d will not be made.			
8.	A translation of the amendmen	ts to the claims under PCT Article 19 (35 U.S.C. 371(c	(3)).		
9.	An oath or declaration of the	inventor(s) (35 U.S.C. 371(c)(4)).			
10.	A translation of the annexes (35 U.S.C. 371(c)(5)).	to the International Preliminary Examination Report Un	der PCT Article 36		
Item	s 11. to 16. below concern other d	ocument(s) or information included:			
11.	An Information Disclosure Sta	tement Under 37 CFR 1.97 and 1.98			
12.	An assignment document for re	cording. A separate cover sheet in compliance with 37	CFR 3.28 and 3.31 is included.		
13.	🔀 A FIRST preliminary amendment				
	A SECOND OF SUBSEQUENT prelim	inary amendment.			
14.	A substitute specification.				
15.	A change of power of attorney	and/or address letter.			
16.	Other items or information: Verified Statement (D. 1.27(b) - Independent Information Disclosur		tus (37CFR 1.9(f) and		

U.S. APPLICATION NO. (If known, see 37 C.)	F 1 501	INTERNATI	ONAL APPLICATION NO.		ATTORNEY DOCK	ET NO.
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17. The following	ng fees are submitted:				CALCULATIONS	PTO USE ONLY
Basic Nation - Search Report h	nal Fee (37 CFR 1.492() las been prepared by th	a)(1)-(5)): he EPO or J	PO	\$ 930.00		
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International p	reliminary examination satisfied provisions o	n fee paid i of PCT Artic	to USPTO (37 CFR 1.48 cle 33(2)-(4)	2) \$ 98.00		
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Claims	Number Filed	-	Number Extra	Rate	***************************************	
Total Claims	3.2	0 =	0	x \$ 22.00	\$	
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			TOTAL NATION	AL FEE =	s 465.00	
Fee for recording the accompanied by an appr	enclosed assignment (3	37 CFR 1.21 37 CFR 3.28	(h)). The assignment, 3.31), \$40 per pro	must be	\$	
			TOTAL FEES EN	CLOSEĎ =	\$ 465.00	
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John C. Kerins,				SIGNATURE	7	
Kerkam, Stowell,	Kondracki & Cla	arke P.C		John C. Ker	ins	
5203 Leesburg Pi Falls Church, VA				32,421 REGISTRATION NO.		
				ACGISTRATION NO.		

Docket: 5860

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

Applicant:

Thierry POURCHEZ

International

Application No.:

7.5°

PCT/FR96/01346

International

Filing Date:

September 4, 1996

U.S. Serial No.:

To Be Assigned

U.S. Filing Date:

March 5, 1998

For: Multilumen Catheter Particularly For Hemodialysis

Falls Church, Virginia

March 5, 1998

PRELIMINARY AMENDMENT

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

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This Preliminary Amendment is filed concurrently with the filing of a Request for entry into national stage examination of the subject patent application. Please amend the application as indicated below.

IN THE SPECIFICATION:

At page 1, after the title of the invention, please insert the following headings:

--BACKGROUND OF THE INVENTION

1. Field of the Invention--.

Page 1, before line 9, please insert the following heading:

-- 2. Description of Related Art--.

Page 1, before line 27, please insert the following heading:

--SUMMARY OF THE INVENTION--.

Page 2, before line 6, please insert the following heading:

-- BRIEF DESCRIPTION OF THE DRAWING--.

Page 2, line 8, after "drawing", delete ", which represents a", and replace with --.--

Page 2, line 9, before "side", please insert --FIG. 1 is a--.

Page 2, before line 11, please insert the following heading:

--DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT--.

IN THE CLAIMS:

- 1. (Amended) A multilumen catheter (1) [of a
- 2 type] comprising:
- at least two inner lumens (2, 3), defined
- by a wall (2A, 3A), each of [which is intended for
- 5 guiding] said inner lumens being adapted to guide at
- 6 least one fluid (4),
- 7 two opposite ends (5, 6), <u>a first</u> one of
- 8 which (5) is [called] a distal end, [since it is] said
- 9 <u>distal end</u> specifically intended to be placed in a cavity

10	of a patient's body [(not represented) in order] and
11	<pre>adapted to deliver and/or sample the fluid (4) to or from</pre>
12	[it] said distal end through at least one channel (7, 8),
13	[the other] a second end (6) being [called] a proximal
14	end, [since it is specifically intended] said proximal
15	end adapted to be connected to a means (9) for
16	circulating fluid (4), [such as a fluid perfusing and/or
17	extracting means,]
18	[this catheter being characterized in that,
19	in order to constitute its] said distal end of said
20	<pre>catheter, [it comprises beyond a so-called] having a</pre>
21	dividing point (12) located at a predetermined distance
22	D1 from [its] <u>said</u> proximal end (6), <u>and having</u> at least
23	two distinct elongated end portions (13, 14) extending
24	<pre>from said dividing point [which:]</pre>
25	[-] wherein said at least two end portions,
26	in at least one rest position of the catheter, extend
27	substantially parallel to [the] \underline{a} longitudinal axis of
28	[this] <u>said</u> catheter, each over a predetermined length
29	(L1, L2) measurable between a free end of said distal end
30	(13A, 14A) and the dividing point (12),
31	[-] wherein said at least two end portions
32	are each made of flexible material so as to be flexible
33	at least under the effect of a lateral action due to the
34	displacement of a fluid, and
35	[- contain] wherein each of said at least

two end portions contains at least one segment of at

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37	least one of the lumens (2, 3) and [have] has at least
38	one channel (7, 8) for delivering and/or sampling the
30	fluid.

1	2. (Amerided) The <u>materialmen</u> eacheder
2	according to claim 1, [characterized in that] wherein:
3	- [the] <u>each of said at least two</u> end
4	portions [have] has a different [lengths] length (L1,
5	L2), and
6	- the channels with which [these] <u>each of</u>
7	said at least two end portions are equipped are [disposed
8	so that each of them] so constructed and arranged such
9	that each emerges at a different [level of] position
LO	along the catheter.

3. (Amended) The <u>multilumen</u> catheter according to claim 2, [characterized in that] <u>wherein</u> the channels with which the <u>at least two</u> end portions are equipped are disposed in a group on each end portion, and [these] <u>wherein said</u> groups are disposed at different [levels of] <u>positions along</u> the catheter.

REMARKS

This Preliminary Amendment is filed to add appropriate headings in the specification to conform the specification to U.S. standards, and to amend the claims

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to bring the claims into a format more familiar to U.S. practice.

Early and favorable consideration on the merits of this application is respectfully requested.

Respectfully submitted,

KERKAM, STOWELL, KONDRACKI & CLARKE, P.C.

John C. Kerins Reg. No. 32,421

Two Skyline Place, Suite #600 5203 Leesburg Pike Falls Church, Virginia 22041 Telephone: (703) 998-3302

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MULTILUMEN CATHETER, PARTICULARLY FOR HEMODIALYSIS

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The invention relates to a device called a multilumen catheter, used for the circulation of a least one fluid between a cavity of a patient's body and a means for circulating this fluid such as a fluid perfusing and/or extracting means.

The invention relates more particularly, though not exclusively, to a catheter for hemodialysis.

The term multilumen catheter designates a catheter comprising at least two inner lumens defined by a wall, each of which is intended for guiding at least one fluid.

A catheter of this type also comprises two opposite ends, one of which is called a distal end since it is specifically intended to be placed in a cavity of a patient's body in order to deliver and/or sample the fluid to or from it through at least one channel, the other being called a proximal end, since it is specifically intended to be connected to a fluid circulating means such as a fluid perfusing and/or extracting means.

With the known catheters, the risk of clogging substances being deposited on the surfaces of the perfusing and/or extracting channels is substantial.

One object of the invention is to obtain a catheter having a risk of obstruction by clogging that is substantially reduced relative to the known catheters.

To this end, the subject of the invention is a catheter of the above-mentioned type, this catheter being characterized in that in order to constitute its distal end, it comprises, beyond a so-called dividing point located at a predetermined distance from its proximal end, at least two distinct elongated end portions which:

- in at least one rest position of the catheter, extend substantially parallel to the longitudinal axis of this catheter, each over a predetermined length measurable between a free end and the dividing point,
 - are each made of flexible material so as to be

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flexible at least under the effect of a lateral action due to the displacement of a fluid,

- contain at least one segment of at least one of the lumens and have at least one channel for delivering and/or sampling the fluid.

The invention will be clearly understood by reading the following description given as a non-limiting example in reference to the appended drawing, which represents a side view of one embodiment of a catheter according to the invention.

The drawing shows an elongated device called a catheter 1 comprising:

- at least two inner lumens 2, 3, defined by a wall 2A, 3A, each of which is intended for guiding at least one fluid 3,

- two opposite ends 5, 6, one of which 5 is called a distal end, since it is specifically intended to be placed inside a cavity of a patient's body (not represented) in order to deliver and/or sample the fluid 4 to or from it through at least one channel 7, 8, the other end 6 being called the proximal end, since it is specifically intended to be connected to a means 9 for circulating a fluid 4, such as a fluid perfusing and/or extracting means.

The fluid 4 is represented by arrows 4.

As shown, the channels 7, 8 are comprised of perforations disposed in the wall of the catheter that defines each of the lumens 2, 3.

These channels allow either the delivery into the area surrounding the catheter of a fluid contained in a lumen of this catheter, or the entry into a lumen of this catheter of a surrounding fluid.

For example, at least one of the lumens is intended for perfusing a fluid and at least one other lumen is intended for extracting fluid.

Also as shown, the lumens 2, 3 for circulating the fluid 4 are for example comprised of juxtaposed lumens,

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but this is not limiting for the invention.

The dimensions and proportions of the catheter represented are not limiting for the invention.

At its proximal end 6, the catheter has elements 10, 11 for connecting each of the lumens 2, 3 it comprises to the means 9 for circulating fluid 4.

As neither the circulating means 9 nor the elements 10, 11 for connecting to this means 9 are subjects of the invention, these elements 10, 11 and the means 9 are not represented in detail.

It is at the distal end 5 that the catheter of the invention is noteworthy.

In effect, in order to constitute its distal end, the catheter comprises, beyond a so-called dividing point 12 located at a predetermined distance D1 from its proximal end 6, at least two distinct elongated end portions 13, 14 which:

- in at least one rest position of the catheter, extend substantially parallel to the longitudinal axis of this catheter, each over a predetermined length L1, L2 measurable between a free end 13A, 14A, and the dividing point 12,
- are each made of flexible material so as to be flexible at least under the effect of a lateral action due to the displacement of a fluid,
- contain at least one segment of at least one of the lumens 2, 3 and has at least one channel 7, 8 for delivering and/or sampling the fluid.

These technical characteristics, when the distal end of the catheter is placed on the axis of a fluid flow such as a bodily fluid flow, allow the end portions, due to their flexibility and independence, to act like a sail set parallel to the wind and thus are practically not subject to obstruction.

In effect, the agitation and flexion of these end portions considerably reduces the risk of clogging substances being deposited on the surfaces of the

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perfusing and/or extracting channels with which these end portions are equipped.

According to another noteworthy characteristic, the end portions have different lengths L1, L2, and the channels with which these end portions are equipped are disposed so that each of them emerges at a different level of the catheter.

According to another characteristic of the invention, the channels with which the end portions are equipped are disposed in a group on each end portion, and these groups are disposed at different levels of the catheter.

CLAIMS

- 1 1. A multilumen catheter (1) of a type comprising:
- 2 at least two inner lumens (2, 3), defined by a wall
- 3 (2A, 3A), each of which is intended for guiding at least
- 4 one fluid (4),
- 5 two opposite ends (5, 6), one of which (5) is called
- a distal end, since it is specifically intended to be
- 7 placed in a cavity of a patient's body (not represented)
- 8 in order to deliver and/or sample the fluid (4) to or
- from it through at least one channel (7, 8), the other
- end (6) being called a proximal end, since it is
- 11 specifically intended to be connected to a means (9) for
- 12 circulating fluid (4), such as a fluid perfusing and/or
- 13 extracting means,
- 14 this catheter being characterized in that, in order to
- 15 constitute its distal end, it comprises beyond a so-
- 16 called dividing point (12) located at a predetermined
- distance D1 from its proximal end (6), at least two
- distinct elongated end portions (13, 14) which:
- in at least one rest position of the catheter extend
- 20 substantially parallel to the longitudinal axis of this
- 21 catheter, each over a predetermined length (L1, L2)
- measurable between a free end (13A, 14A) and the dividing
- 23 point (12),
- are each made of flexible material so as to be
- 25 flexible at least under the effect of a lateral action
- 26 due to the displacement of a fluid,
- 27 contain at least one segment of at least one of the
- lumens (2, 3) and have at least one channel (7, 8) for
- 29 delivering and/or sampling the fluid.
 - 1 2. The catheter according to claim 1, characterized in
- 2 that:
- the end portions have different lengths (L1, L2),
- 4 and

- the channels with which these end portions are equipped are disposed so that each of them emerges at a different level of the catheter.
- 3. The catheter according to claim 2, characterized in that the channels with which the end portions are equipped are disposed in a group on each end portion, and these groups are disposed at different levels of the catheter.

ABSTRACT

A multilumen catheter (1) of a type comprising two inner lumens (2, 3) defined by a wall (2A, 3A) for guiding a fluid (4), and two opposite ends (5, 6), namely a distal end (5) and a proximal end (6), characterized in that the distal end is formed of two elongated and discrete end portions (13, 14) located beyond a so-called dividing point (12) at a predetermined distance D1 from the proximal end (6), wherein said end portions, in a rest position of the catheter, extend parallel to the longitudinal axis thereof, each over a predetermined length (L1, L2) measurable between a free end (13A, 14A) and the dividing point (12), are each made of a flexible material, contain a segment of at least one lumen (2, 3) and have at least one channel (7, 8) for delivering and/or sampling the fluid.

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French Language Declaration

POUVOIR: En tant qu'inventeur, je désigne l'(les) avocat(s) et/ou l'(les) agent(s) suivant(s) pour poursuivre la procédure de cette demande et traiter toute affaire la concernant supris du Bureau des Brevets et de Marques:

Harold L. Stowell, Reg. 17,233 Edward J. Kondracki, Reg. 20,604 Dennis P. Clarke, Reg. 22,549 William L. Feeney, Reg. 29,918 John C. Kerins, Reg. 32,421 POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (list name and registration number)

Harold L. Stowell, Reg. 17,233 Edward J. Kondracki, Reg. 20,604 Dennis P. Clarke, Reg. 22,549 William L. Feeney, Reg. 29,918 John C. Kerins, Reg. 32,421

Adresser toure correspondance à:

KERKAM, STOWELL, KONDRACKI & CLARKE, P.C. 5203 Leesburg Pike, Suite 600 Falls Church, VA 22041

Adresser toute communication téléphonique à: (Nom) (Numéro de téléphone)

(703) 998-3302

Send Correspondence to:

KERKAM, STOWELL, KONDRACKI & CLARKE, P.C. 5203 Leesburg Pike, Suite 600 Falls Church, VA 22041

Direct Telephone Calls to: (name and telephone number)

(703) 998-3302

Inventor's signature Residence Citizenship Post Office Address	Date
Residence Citizenship	Date
Citizenship	
Post Office Address	
Full name of second joint inventor, if any	
Tall hand or cooking joint account, a cary	
Second Inventor's signature	Date
Residence	
Citizenship	
Post Office Address	
	Residence Citizenship

(Fournir les mêmes renseignements et la signature de tout ∞ -inventeur supplémentaire.)

(Supply similar information and signature for third and subsequent joint inventors.)

Page 3 of 3

Patent and Trademark Office-U.S. DEPARTMENT OF COMMERCE

and the first time that the court will be a single court of the court

French Language Declaration

Je revendique par le présent acte le bénéfice de priorité étrangère selon Titre 35, du Code des Etats-Unis, §119 de toute demande de brevet ou d'attestation d'inventeur énumérée ci-après, et j'ai identifié également ci-après toute demande étrangère de brevet ou d'attestation d'inventeur ayant une date de dépôt antérieure à celle de la demande pour laquelle la priorité est revendiquée.

I hereby claim foreign priority benefits under Title States Code, §119 of any foreign application(s) for inventor's certificate listed below and have also below any foreign application for patent or inventor cate having a filing date before that of the applica which priority is claimed:

y claimed				lications	Prior foreign appli
de priorité endiqué			ans un autre pays:	revet anterieure(s) dan	-
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below and, tims of this tates appli- aph of Title the duty to 17, Code of etween the	application(s r of each o n the prior to d by the firs 12, I ackno as defined which occ ation and the	I hereby claim the benefit und §120 of any United States a insofar as the subject matter application is not disclosed in cation in the manner provide 35, United States Code, §1 disclose material information Federal Regulations, §1.56 filling date of the prior application international filling date of this	(s) demande(s) amé- la mesure où le sujet le demande n'est pas ntérieure, de la façon litre 35 du Code des r de divulguer l'infor- ode des Réglements ui se présente entre re et la date de dépôt	le présent acte, le béne de-Unis, §120 de toute(s) (s) ci-après et, dans la evendications de cette de emande américaine ante- nier paragraphe de Titri de reconnais le devoir de selon Titre 37 du Code , toute information qui la demande antérieure sit nationale, soit interna	du Code des Etats- ricaines énumérée(de chacune des rev divulgué dans la der dèfinie par le premi Etats-Unis, §112, je mation pertinente s Fédéraux, §1.56 la date de dépôt de l
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Je déclare par le présent acte que toutes mes déclarations, à ma connaissance, sont vraies et que toutes les déclarations faites à partir de renseignements ou de suppositions, sont tenues pour être vraies; de plus, toutes ces declarations ont été faites en sachant que de fausses déclarations volontaires u autres actes de même nature sont sanctionées par une amende ou un emprisonnement, ou les deux, selon la Section 1001, du Titre 18 de Code des Etats-Unis et que de selles déclarations délibérément fausses peuvent compromettre la validité de la demande ou du brevet délivré.

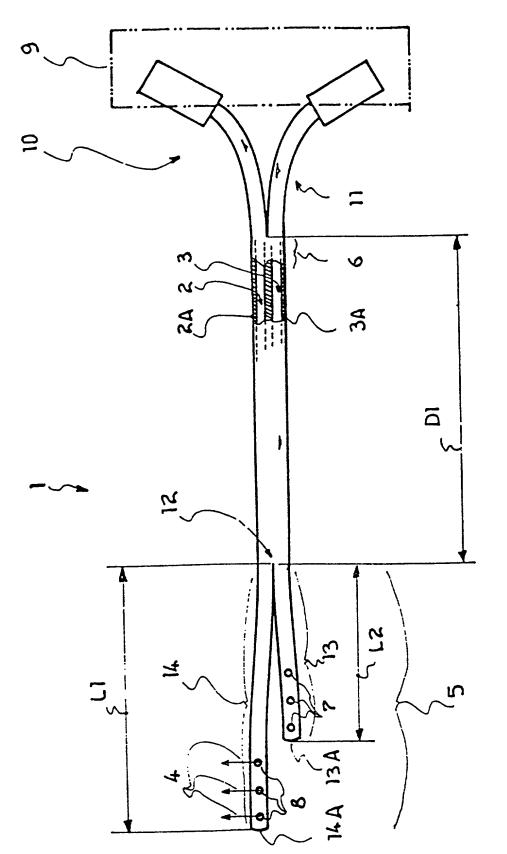
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Declaration and Power of Attorney For Patent Application Declaration Pour Demandes de Brevets Avec Pouvoirs

French Language Declaration

En tant qu' inventeur nomme ci-après, Je déclare par le pré- sent acte que:	As a below named inventor, I hereby declare that:
Mon nom, mon domicile, mon adresse postale, ma nationalité sont ceux qui figurent ci-après,	My residence, post office address and citizenship are as stated below next to my name,
Je déclare que je crois être l'inventeur original, premier et unique (si un seul nom figure sur le présent acte) ou un des co-inventeurs, originaux et premiers (si plusieurs noms figurent sur le present acte) du sujet revendiqué et pour liquel un brevet est demande sur la base de l'invention intitulée:	I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled MULTILUMEN CATHETER, PARTICULARLY FOR HEMODIALYSIS
dont la description (cocher la case correspondante)	the specification of which (check one)
est annexée au présent acte.	is attached hereto.
a été déposée	was filed on as
Numéro de série de la demande	Application Serial Noas
et modifiée le	
et modifiée le(si approprié)	and was amended on(if applicable)
Je déclare par le présent acte avoir examiné et compris le contenu de la description identifiée ci-dessus, revendications y compris, et le cas échéant telle que modifiée par l'amendment cité plus haut.	I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.
Je reconnais le devoir de divulguer l'information qui est en rapport avec l'examen de cette demande selon Titre 37 du Code des Reglements Fédéraux §1.56 .	I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56.
Page 1	of 3

Applicant or Patentee:	POURCHEZ Thierry .eAtto	orney's tet No.
	TER PARTICULARY FOR HEMO	
VERIFIED STATE	MENT (DECLARATION) CLAIMIN 1.9(f) and 1.27(b)) - INDE	IG SMALL ENTITY
independent inventor as or reduced fees under section to the Patent and Trademo	r, I hereby declare that I defined in 37 CFR 1.9(c) f on 41(a) and (b) of Title ark Office with regard to [] Patent	for purposes of paying 35, United States Code, the invention described
obligation under contrac- rights in the invention independent inventor under invention, or to any con-	nted, conveyed or licensed t or law to assign, grant, to any person who could no er 37 CFR 1.9(c) if that p cern which would not quali (d) or a nonprofit organiz	convey or license, any or be classified as an error had made the fy as a small business
conveyed, or licensed or	organization to which I ha am under an obligation un r license any rights in th	der contract or law to
[x] no suc	ch person, concern, or org ns, concerns, or organizat	ranization tions listed below*
*NOTE: Separate verified concern or organization lateral status as small entities	d statements are required having rights to the inven	from each named person, tion averring to their
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